Robert M. Goodman, Esq.
GREENBAUM, ROWE, SMITH & DAVIS LLP
75 Livingston Avenue, Suite 301
Roseland, New Jersey 07068
Telephone: (973) 535-1600
Facsimile: (973) 535-1698
Attorneys for Plaintiff,
Teva Women's Health, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA WOMEN'S HEALTH, INC., **Plaintiff,** **v.** **LUPIN, LTD.,** **and** **LUPIN PHARMACEUTICALS, INC.** **Defendants.**	**Civil Action No. _____**

COMPLAINT

Plaintiff Teva Women's Health, Inc. ("Teva Women's Health"), formerly known as Duramed Pharmaceuticals, Inc., for its Complaint against Defendants Lupin, Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin Pharma") (collectively, "Lupin") alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the Patent Laws of the United States, Title 35, United States Code, Sections 1 *et seq.*

THE PARTIES

2. Plaintiff Teva Women's Health is a corporation organized and existing under the laws of the State of Delaware, having an established place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677. Teva Women's Health is a proprietary pharmaceutical company that has been an innovator in the area of women's health. Teva Women's Health focuses on researching, developing, and providing patients with an array of female healthcare products, with particular emphasis on developing and marketing products that serve the reproductive and menopausal needs of women.

3. On information and belief, Defendant Lupin Pharma is a corporation organized under the laws of the Commonwealth of Virginia, with a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. On information and belief, Lupin Pharma is registered to do business in New Jersey and is a wholly owned subsidiary of Lupin Ltd. Accordingly, this Court has jurisdiction over Defendant Lupin Pharma.

4. On information and belief, Defendant Lupin Ltd. is a corporation organized under the laws of India, with a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Lupin Ltd. develops, manufactures, markets and sells generic pharmaceutical products and distributes those products throughout the United States and in this District, including through Lupin Pharma. Accordingly, this Court has personal jurisdiction over Defendant Lupin Ltd.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Defendants Lupin Ltd. and Lupin Pharma because, *inter alia*, Lupin Ltd. and Lupin Pharma have purposefully availed themselves of the rights and benefits of New Jersey law. Upon information and belief, Defendant Lupin Ltd. and Lupin Pharma engage in the manufacture and sale of a range of generic pharmaceutical products within the United States generally and the State of New Jersey specifically.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), and 1400(b) because Defendants Lupin Ltd. and Lupin Pharma are subject to personal jurisdiction in this District.

BACKGROUND

8. On September 25, 2007, the United States Patent and Trademark Office ("USPTO") duly and legally issued U.S. Patent No. Re. 39,861 ("the '861 patent"), entitled "Methods of Extended Use Oral Contraception," to Duramed Pharmaceuticals, Inc., now known as Teva Women's Health, Inc. The '861 patent names Gary D. Hodgen as the inventor. The '861 patent is valid and enforceable and does not expire until June 23, 2017. Teva Women's Health is the sole owner of the '861 patent and has the sole right to sue and to recover for any past, present or future infringement of that patent. A copy of the '861 patent is attached hereto as Exhibit A.

9. The '861 patent is directed to, *inter alia*, a method of female contraception that reduces the number of menstrual periods per year, which comprises, *inter alia*, orally monophasicly administering a combination of estrogen and progestin for 84 consecutive days, followed by administration of a placebo for a period of 7 days, wherein the combination of estrogen and progestin and the placebo are packaged together in a kit.

10. On September 5, 2003, the United States Food and Drug Administration ("FDA") approved Teva Women's Health's New Drug Application ("NDA") No. 21-544, allowing Teva Women's Health to sell under the trade name Seasonale® the first extended regimen oral contraceptive available in the United States. The active ingredients of Seasonale® comprise a combination of ethinyl estradiol, 0.03 mg, and levonorgestrel, 0.15 mg. Seasonale® was the first product to allow women to reduce the number of menstrual periods from 13 to 4 per year.

11. The '861 patent is listed in the FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book") as covering the Seasonale® product.

12. Teva Women's Health sells one or more drug products under the trade name Seasonale® in the United States pursuant to NDA No. 21-544. The approved use of such products is claimed by the '861 patent.

ACTS GIVING RISE TO THIS ACTION

13. By letter dated August 24, 2009 ("Notice Letter"), Lupin Ltd. notified Teva Women's Health that Lupin Ltd. had submitted Abbreviated New Drug Application ("ANDA") No. 91-440 to the FDA seeking approval to manufacture, sell, and distribute a generic version of Teva Women's Health's Seasonale® extended regimen contraceptive product.

14. Accoridng to the Notice Letter, the purpose of Lupin's filing of the ANDA is to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, and sale of a generic version of Seasonale® to be sold in a kit containing 84 active tablets (comprising a combination of ethinyl estradiol, 0.03 mg, and

levonorgestrel, 0.15 mg) and 7 placebo tablets packaged together ("the Lupin Product") prior to the expiration of the '861 patent.

15. Lupin Ltd. submitted its ANDA to the FDA containing a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Lupin Ltd.'s opinion, the '861 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the Lupin Product. Lupin Ltd.'s filing of the ANDA with the Paragraph IV certification infringed the '861 patent under 35 U.S.C. § 271(e)(2).

16. Lupin Ltd.'s Notice Letter indicates that in filing its ANDA, Defendant Lupin Ltd. intends to engage in the commercial manufacture, use, and sale of the Lupin Product (including, upon information and belief, commercial sale of such a product in the State of New Jersey) prior to the expiration of the '861 patent in the event that the FDA approves Lupin Ltd.'s ANDA.

17. Upon information and belief, Lupin Ltd. intends to continue to pursue approval of its ANDA by the FDA.

18. Lupin Ltd. was aware of the '861 patent when it filed ANDA No. 91-440 including the Paragraph IV certification.

19. Teva Women's Health commenced this action within 45 days of the date it received the Notice Letter dated August 24, 2009, regarding Lupin Ltd.'s submission of its ANDA containing the Paragraph IV certification to the FDA.

COUNT I: PATENT INFRINGEMENT

(U.S. Patent No. Re. 39,861)

20. Paragraphs 1 through 18 are incorporated by reference as if restated fully herein.

21. Upon information and belief, Lupin Ltd.'s filing of its ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a generic version of the Seasonale® extended regimen oral contraceptive product prior to the expiration of the '861 patent infringed, and its maintenance of that ANDA continues to infringe, the '861 patent under 35 U.S.C. § 271(e)(2).

22. Upon information and belief, the use of the Lupin Product in accordance with, and as directed by, the proposed product labeling prior to the expiration of the '861 patent would infringe the '861 patent.

23. Upon information and belief, upon FDA approval of Lupin Ltd.'s ANDA, Lupin Ltd. and Lupin Pharma intend to manufacture the Lupin Product and to offer for sale, sell and distribute the Lupin Product in the United States.

24. Upon information and belief, Lupin Ltd. and Lupin Pharma know that the Lupin Product and its product labeling are especially made or adapted for use in infringing the '861 patent and that the Lupin Product and its product labeling are not suitable for substantial noninfringing use.

25. Unless Lupin Ltd. and Lupin Pharma are enjoined from infringing the '861 patent, Teva Women's Health will be substantially and irreparably harmed by, and will suffer damages as a result of, Lupin Ltd.'s and Lupin Pharma's actions.

26. Upon information and belief, Lupin Ltd. and Lupin Pharma acted without a reasonable basis for believing that they would not be liable for infringement of the '861 patent.

27. Lupin Ltd.'s and Lupin Pharma's conduct render this case "exceptional" as described in 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, plaintiff Teva Women's Health respectfully requests the following relief:

A. A permanent injunction barring Lupin Ltd. and Lupin Phama and their officers, agents, and employees, and all persons acting in concert with Lupin Ltd. or Lupin Pharma, from infringing United States Patent No. Re. 39,861 by making, using, selling, offering to sell, marketing, importing, or distributing any oral contraceptive product, including the product described in Lupin Ltd.'s ANDA No. 91-440;

B. An order decreeing the effective date of any approval of Lupin Ltd.'s ANDA No. 91-440 to be a date which is not earlier than the expiration date of United States Patent No. Re. 39,861;

C. A final judgment declaring that Lupin Ltd.'s and Lupin Pharma's manufacture, sale, offer for sale, marketing and distribution in, or importation into, the United States of the product described in Lupin Ltd.'s ANDA No. 91-440 will infringe, induce infringement, and contribute to the infringement of United States Patent No. Re. 39,861;

D. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285 and an award to Teva Women's Health of its attorneys' fees, costs, and expenses incurred in prosecuting this action; and

E. Such other and further relief as this Court may deem just and proper.

Dated: October 6, 2009

Respectfully submitted,

/s/ Robert M. Goodman
Robert M. Goodman, Esq.
GREENBAUM, ROWE, SMITH & DAVIS LLP
75 Livingston Avenue, Suite 301
Roseland, New Jersey 07068
Telephone: (973) 535-1600
Facsimile: (973) 535-1698

Of Counsel:

Daniel F. Attridge, P.C.
Charanjit Brahma
Corey J. Manley
Michael D. Shumsky
Nathan S. Mammen
Michael A. Pearson
Leslie M. Schmidt
KIRKLAND & ELLIS LLP
655 Fifteenth Street, N.W.
Washington, DC 20005
Telephone: (202) 879-5000
Facsimile: (202) 879-5200

Attorneys for Plaintiff
Teva Women's Health, Inc.